



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
CARIBBEAN ENVIRONMENTAL PROTECTION DIVISION
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GUAYNABO, PR 00968-8069

MAY - 8 2017

MAY 09 2017

CERTIFIED MAIL /RETURN RECEIPT REQUESTED

Article Number: 7015 0920 0000 8688 5085

Mr. Alvin E. Crespo
Director
Environmental Health and Safety
Bristol-Myers Squibb Manufacturing Company
Humacao Operations
P.O. Box 609
Humacao, Puerto Rico, 00792-1255

Re: Technical Review January 13, 2017 RCRA Corrective Action Program Quarterly Progress Report No. 65 4th Quarter 2016 for the Bristol-Myers Squibb Manufacturing Company, Humacao, Puerto Rico
EPA ID Number: PRD 090021056

Dear Mr. Crespo:

The United States Environmental Protection Agency-Region 2 (EPA) has reviewed the January 13, 2017 RCRA Corrective Action Program Quarterly Progress Report No. 65 4th Quarter 2016 (Report), submitted by Bristol-Myers Squibb Manufacturing Company (BMSMC) for its facility in Humacao, Puerto Rico. Enclosed are the EPA's comments on the Report. Please provide your response to the enclosed comments within 60 days of receipt of this letter. If you have any questions regarding this correspondence, please contact Socorro Martinez of my staff at (787) 977-5886 or via email at martinez.socorro@epa.gov.

Sincerely,

Carmen R. Guerrero-Pérez
Director
Caribbean Environmental Protection Division

cc: Manuel O. Claudio Rodriguez, Manager,
Land Pollution Control Program, PREQ

Enclosure

**Technical Review January 13, 2017 RCRA Corrective Action Program Quarterly Progress Report No. 65
4th Quarter 2016 for the Bristol-Myers Squibb Manufacturing Company, Humacao, Puerto Rico
EPA ID Number: PRD 090021056**

I. GENERAL COMMENTS

1. C9-C10 aromatics, C9-C12 aliphatics, C11-C22 aromatics, C19-C36 aliphatics, C9-C18 aliphatics were systematically detected at low-levels (i.e., above the method detection limit (MDL) but below the reporting limit (RL)) in the laboratory method blanks and as a result several sample results were qualified with a B-flag. The Release Assessment Quality Assurance Project Plan (QAPP) Worksheets #28-5 and #28-6 indicate that the laboratory was directed to conduct corrective action when the contaminants of concern results are greater than the MDL. All of the analytical batches for the volatile petroleum hydrocarbons (VPH) and extract petroleum hydrocarbon (EPH) analyses for the 3rd Quarter 2016 were affected by this method blank contamination; yet the laboratory case narratives do not mention corrective action undertaken. BMSMC should work with the analytical laboratory to seek out the potential source(s) of method blank contamination and resolve this issue for future rounds of sampling and analysis.
2. The Release Assessment QAPP Worksheet #36 does not specify the validation procedure for VPH and EPH analysis. However, the data validation reports in Appendix A of the RCRA Corrective Action Program Quarterly Progress Report No. 65 4th Quarter 2016 indicate that the B-flag applied by the laboratory due to method blank contamination was retained for all the associated sample results regardless of the sample concentration. Typically, during data validation the B-flag is removed if the sample concentration is greater than five times the method blank concentration because the sample concentration is not considered an artifact of the method blank contamination at that level. Also note that B-flag results are of concern for data usability as B-flagged data are not considered usable data for risk assessment. Thus, it is encouraged that BMSMC re-evaluate B-flagged data and remove the B-flags where the sample concentration is greater than five times the method blank concentration.

II. SPECIFIC COMMENTS

Tables 1 through 4

3. Several non-detect sample results (e.g., benzene result for MW-19) presented on Tables 1 through 4 had elevated detection limits above the U.S. EPA maximum contaminant level (MCL) or U.S. EPA Regional Screening Levels (RSLs) due to sample dilution. These sample results should also be shaded and footnotes provided which indicate that the elevated detection limit exceeds the MCL or RSL due to the presence of other target analytes that required sample dilution.

Attachment B 3rd Quarter 2016 Groundwater Sampling Field Data Sheets

Copies of the field logbook were provided in Attachment B, but many of the pages were not legible. Since legible field logbooks are an essential data verification element and part of the project file, BMSMC should remind the field crew to write clearly in the logbooks during